Transcript of February 21, 2001 Meeting

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AMBULATORY BLOOD PRESSURE MONITORING

Baltimore Convention Center
Baltimore, Maryland

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Panelists

Chairperson
Harold C. Sox, MD

Vice-Chairperson
Ronald M. Davis, MD

Voting Members
Willarda V. Edwards, MD
Karl A. Matuszewski, MS, PharmD
Wade M. Aubry, MD

Temporary Voting Members
Kenneth P. Brin, MD, PhD

Temporary Nonvoting Guest
Parker J. Staples, MD

Consumer Representative
Christine M. Grant, JD

Industry Representative
Eileen C. Helzner, MD

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Panelists (Continued)

Director, Coverage and Analysis Group, HCFA
Sean R. Tunis, MD, MSc

Executive Secretary
Patricia Brocato-Simons

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TABLE OF CONTENTS

P R O C E E D I N G S

MS. BROCATO-SIMONS: Good morning. We would like to call the meeting to order please.

Good morning and welcome, panel chairperson, panel members, co-workers and guests. My name is Patricia Brocato-Simons, executive secretary of the Medical Devices and Prosthetics

Panel of the Medicare Coverage Advisory Committee. The panel is here today to provide advice and recommendations to the Health Care Financing Administration regarding the use of ambulatory blood pressure monitoring for the diagnosis and treatment of hypertension.

At the conclusion of today's meeting, the panelists will be asked to vote on a series of questions. The answers to those questions will constitute the panels recommendations, which will be submitted to the Executive Committee when it next meets. Once the Executive Committee makes its recommendations and forwards those recommendations to HCFA, HCFA has the responsibility to develop a coverage policy within 60 days of receipt of that recommendation.

For the purposes of today's meeting, Dr. Kenneth Brin, a current member of the Medical and

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Surgical Procedures Panel of the Medicare Coverage Advisory Committee and a board certified cardiologist, received an appointment of temporary

voting member.

Dr. Parker Staples, the medical director of the durable medical equipment regional carrier for the state of Rhode Island --

DR. STAPLES: I am contractor medical director, not the medical director.

MS. BROCATO-SIMONS: I apologize, contractor medical director, excuse me, received an appointment of temporary not nonvoting guest, and Miss Christine Grant, a current member of the Drugs, Biologics and Therapeutics Panel of the Medicare Coverage Advisory Committee and Commissioner of Health and Senior Services for the state of New Jersey, received an appointment of temporary nonvoting guest.

The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record to preclude even the appearance of impropriety. To determine if any conflict existed, HCFA received a submitted agenda and all financial interests reported by the

panel participants. The conflict of interest

statutes prohibit special government employees from participating in matters that could affect their or their employers financial interests. HCFA has determined that all members and consultants may participate in the matters before the panel today. With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firm whose products or services constitute any portion of their presentation.

And now I would like to turn the meeting over to the Director of the Coverage and Analysis Group of the Health Care Financing Administration, Dr. Sean Tunis.

DR. TUNIS: Good morning. I just want to make a couple comments. One is just to pick up on what Patricia just said about the disclosure and conflict of interests. I think it would also be helpful as the panel introduces themselves and as

each of the speakers introduces themselves, to describe any previous involvement with development of position statements or any sort of advocacy related to ambulatory blood pressure monitoring, and any significant previous academic published work in that

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area, obviously not paper by paper, but any previous activities involved in some kind of policy development related to blood pressure monitoring.

The other topic I just wanted to cover briefly was an explanation of the reason that this was, this topic was referred to the Medicare Coverage Advisory Committee. As you know, of the large number of requests for coverage that we get at the national level, only a subset are referred for any discussion by the coverage advisory committee. I think the brief explanation for why we thought this would be helpful to have advice from the committee was that quickly in reviewing the available published literature, two things became quite clear, at least to HCFA staff.

One was that over the last decade or more, the accuracy and reliability of ambulatory blood pressure monitoring has become quite good and the FDA approval of these devices has gone a long way towards insuring the technical quality of the information produced. So we had no discomfort at all with coming to that conclusion, and the FDA approval of these devices I think is adequate demonstration of that.

What's similarly quite clear is that as you read through the literature, a comment that comes

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out through all the papers including the ones published in 2000 is the importance of longitudinal data that would show the impact on clinical outcomes of the use of ambulatory blood pressure monitoring and comparing that to management of patient without ambulatory blood pressure monitoring, and most commentators observe that such a definitive study, a longitudinal study, has not actually been done.

So in the absence of having the definitive direct proof of the benefit and clinical outcomes of the ambulatory blood pressure monitoring, we are left

with a large amount of other studies that, some of which are supportive and some of which are not supportive of the use, and this is the sort of situation in which it's very helpful to have the advisory committee's input. So that briefly explains why we came to the conclusion that it would be useful to have this come before the committee.

And with that, I would like to turn the meeting over to Dr. Harold Sox, who is the chairman of the Medicare Coverage Advisory Committee.

DR. SOX: Thank you, Sean. My name is Harold Sox -- can you hear me -- and I am chair of the Department of Medicine at Dartmouth-Hitchcock Medical Center and I am chair of the panel, and what

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I will ask each member of the panel, both temporary and permanent and voting and nonvoting to introduce themselves and then as Sean requested, to give their history with this topic.

My history with this topic is that I was chair of the American College of Physicians clinical

efficacy assessment subcommittee at the time that it reviewed the topic of ambulatory blood pressure monitoring and for those who read the background material, you will note that we basically found that the evidence was insufficient to recommend ambulatory blood pressure monitoring.

I should also mention that although I am currently chair of the department at Dartmouth, as of July 1st I will be editor of a medical journal called the Annals of Internal Medicine. This is a journal that accepts advertising.

DR. DAVIS: I am Ron Davis, I am director of the Center for Health promotion and Disease Prevention at the Henry Ford Health System, and I have had no prior experience of note related to this topic.

DR. EDWARDS: Willarda Edwards, internist in Baltimore, and I have had no prior experience with ambulatory blood pressure monitoring.

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DR. MATUSZEWSKI: Karl Matuszewski, senior director of the Clinical Knowledge Service at the

University Health Service Consortium, which is an alliance of 85 academic health centers. I do have some previous experience with this technology. In 1990 I was the author of a review on ambulatory blood pressure monitoring for Blue Cross and Blue Shield Association's Technology Evaluation Center. I have to admit that in the decade plus since I have not followed the topic, but quickly became reacquainted with some of the literature in the last few weeks.

DR. AUBRY: I am Wade Aubry. I'm an internist and endocrinologist in San Francisco, I'm a consultant to the Blue Cross/Blue Shield Association, and to the Health Technology Center which is a new start-up, nonprofit organization in San Francisco. My past experience with this topic includes a review for Blue Shield of California when I was medical director there in the early 1990s. I was also chairman of the Blue Cross/Blue Shield Association Technology Evaluation Center medical advisory panel in 1998 or '99, when that review was done, and that's part of the agenda materials.

DR. BRIN: I'm Ken Brin. I am a practicing cardiologist with the Summit Medical Group

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in Summit, New Jersey. I am former chairman of our board, medical director and former CEO of our group. As a practicing cardiologist, I do not do ambulatory blood pressure monitoring myself; that's done by our renal group, so I have no direct financial benefit from this. I probably order one or two a year on a clinical basis, but don't use that to enhance my reading of the literature.

DR. STAPLES: As stated, Parker Staples, Providence, Rhode Island. I am the contractor medical director, I have been in this position since 1989. I have no outside experience nor knowledge of this particular technology other than the materials that were provided as the basis for this meeting.

MS. GRANT: Christine Grant, Commissioner of Health and Senior Services of New Jersey. I have no direct relationship to ABPM. However, I would disclose that in the early '90s I worked for a pharmaceutical company which at that time and today

has an antihypertensive medication and obviously as Commissioner of Health and Senior Services am involved in a variety of activities that promote public awareness and access to hypertensive prevention and therapy.

DR. HELZNER: Eileen Helzner, vice

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president Worldwide Clinical Development and Outcomes Research for Johnson & Johnson, working with our medical device and diagnostic companies. I am a physician by training, also an epidemiologist outcomes researcher, and do not have any direct relationship with this particular project.

DR. SOX: Thank you. At this point I'm going to give the charge to the committee. Will you be able to hear me if I don't have the mike? Well, the interim guidelines for the Medicare Coverage Advisory Committee charge the committee with advising HCFA on the quality of the evidence for the technology under consideration. And our guidelines state that first we have to look at, we have to

examine the validity of the evidence, basically examining whether the technology in question is responsible for the health outcomes that have been measured or whether some other variable might be contributing to those health care outcomes so that we either over or underestimate the contribution of the technology itself to the health care outcome.

And assuming that we can find that we have valid evidence, then we have to focus on the size of the health effect, whether it's a major breakthrough technology or really not much effect at all. So, our

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job will be to focus on validity and effect size. Now this is a very complicated topic for which we have a relatively small amount of time to discuss. The committee that I chaired for the American College of Physicians probably spent a total of six or eight committee hours discussing this topic, so we're not going to have a lot of time to talk.

And so in an effort to try to focus the discussion on the key pieces of evidence, I have created something called an analytic framework for

trying to dissect out the logical steps between ABPM on the one hand and health care outcomes on the other. This is a technique that's used by the U.S. Preventive Services task force on which I currently serve, and it has helped a lot. So I'm going to go briefly through the analytical framework with the three questions that we have been assigned to evaluate and then to focus on the key questions that we're going to try to let the evidence answer for us, if we can.

So the major focus of our attention because that's where most of the evidence lies, is in the management of something called white coat hypertension, which in brief is, somebody who has white coat hypertension has en elevated blood

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pressure in the office, and a relatively normal or even normal blood pressure at home. Presumably, the white coat is the doctor's white coat and it causes the patient to get excited and to raise the blood pressure.

So here's our analytic framework. And it starts with somebody who is suspected of having white coat hypertension, it involves an intervention, ABPM, and then it involves some health care outcomes that are important to people, mainly stroke and coronary artery disease on the one hand, and the side effects of medication on the other.

Now, one approach to evaluating the effect of ABPM would simply be to take a group of patients who have white coat hypertension, that is to say abnormal blood pressure in the office, normal blood pressure at home, and treat them either on the basis of their blood pressure at home or on the basis of their blood pressure in the office, and in addition have a control group, a normal group who have normal blood pressure in the office, and then measure these health care outcomes. So effectively you would be testing the hypothesis that treating people who have normal blood pressure at home, or not treating them gives the same effect, health care effects, as

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somebody who has normal blood pressure both at home

and at the office.

This type of study hasn't been done. There has been one randomized trial of the use of ABPM in the management of hypertension but it really didn't address this question, and we will go over that later on.

So another approach to trying to link up ABPM and these health care outcomes is to kind of go through the steps that one should go through in thinking through the problem, so we could first ask ourselves, does ABPM actually identify people who have blood pressure that's elevated in the office but normal at home, does it do what it's supposed to do? We then could ask ourselves, well, given the information about a person having normal blood pressure at home even though the blood pressure is elevated in the office, do doctors actually withhold treatment, are they actually willing to treat people the same way whether they have normal blood pressure in the office or a normal blood pressure at home.

Now, if physicians in fact are willing to

withhold treatment from people whose blood pressure is up in the office and normal at home, that could have some effects on intermediate outcomes, that is,

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outcomes that predict the outcomes that are most important to us but aren't actually outcomes you could experience. So for example, the mass of the left ventricle is a measure of the severity of hypertension and it's a good predictor of these bad outcomes. So you could ask yourself, do people who have white coat hypertension who are untreated, do they have the same intermediate outcomes, the same size of the left ventricle, the same amount of atherosclerotic plaque in the vessels of the neck, as people who have normal blood pressure and who aren't treated.

And then finally you could ask, does the degree of left ventricular mass or carotid plaque in people with white coat hypertension predict that the health care outcomes they experience will be similar to people with normal office blood pressure who aren't treated.

So that's sort of the logic that we will try to work our way through during the time we have to discuss this topic among the panel. Now the second issue that we have been asked to address is the question of treatment resistant hypertension and the specific question is do people who have an elevated blood pressure on treatment in the office,

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is there a subgroup of those patients whose blood pressure is perfectly fine at home and therefore don't need to have continual increase in their blood pressure medication doses or changing to new blood pressure medication. Very important questions.

So here we could, the question, the way this presents is treatment that is not successful in controlling blood pressure as measured in the office, you could do ABPM in these patients and then take the patients whose blood pressure is perfectly well controlled at home and randomize those patients to either get no treatment or to continue to have medication adjustments according to their office

blood pressure, and then measure their health care outcomes. Again, although there is a randomized trial in the management of treatment of resistant hypertension as you will see, it doesn't directly address the issue of health care outcomes in people whose blood pressure is well controlled at home but not in the office who then are treated on the basis of their home blood pressures.

So again, we could ask ourselves, going through this logic of the analytic framework, if you do ABPM, could you identify a subgroup of patients whose blood pressure is fine at home even though it's

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still out of treatment goal in the office, and if you can, are physicians willing to maintain their treatment on the basis of home blood pressure instead of increasing the blood pressure medication because the office blood pressure is elevated.

And finally we could ask ourselves, in those patients who have normal, have well controlled blood pressure at home but not in the office, whose treatment is maintained without increasing it as

would be appropriate for their office blood pressure, are their health care outcomes similar to people whose blood pressure is well controlled on the basis of office blood pressure measurements.

So we'll examine this analytic framework in the second part of our discussion, spending less time on it simply because we have less evidence.

Now the third issue we have been asked to address is the question about symptoms of low blood pressure on medication. Some patients who are on high blood pressure medication, if they stand up suddenly, they will get a little bit dizzy, which probably reflects a transient drop in their blood pressure because of the type of medication they take, and it's important to identify such patients and be able to change their medications appropriately. And

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so, one of the questions we've been asked to look at is whether we can identify patients whose blood pressure drops on medication at home, who then might be appropriately treated with another medication, and

so the approach we are going to take there, the logic here is if you have symptoms of low blood pressure on treatment, you could check for low blood pressure and the production of symptoms when the blood pressure falls in the office. If the patients blood pressure falls in the office and they get dizzy, then you could change the treatment regimen and you could measure the effect of changing the treatment regimen on health care outcomes, such as the symptoms which prompted you to change the blood pressure medication, as well as some of the long-term health effects.

Now there may be a subgroup of patients who despite having low blood pressure on medication at home don't have it in the office, and for these patients, it might be appropriate to do ambulatory blood pressure monitoring and if they have low blood pressure upon standing at home to change their treatment regimen and then measure the health care outcomes, both symptoms as well as long-term effect. And so the real question is, how much gain do you get when you do ambulatory blood pressure monitoring at

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home in patients who have these symptoms but don't drop their blood pressure when you check it in the office, in other words, what is the gain or the margin if any, of ambulatory blood pressure monitoring on health care outcomes, probably focusing on symptoms.

So, there's our charge for the day, to try to dissect out the evidence that deals with this question and deal with such key questions as for example on this last one, to focus on the key questions that relate to this analytic framework. And then ultimately to take a vote on whether the evidence that is out there is sufficient to draw conclusions and give HCFA advice about that.

So, with that, I'll stop and we'll get into the main part of the meeting. Any questions about the analytic framework before we get started? Ron.

DR. DAVIS: Hal, just a couple of questions that occurred to me as I reviewed the material and tried to analyze them in the context of

the framework. On the first one, white coat hypertension, one issue that comes up in regard to key question number 2 is what about physicians who don't withhold treatment completely but reduce

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treatment, reduce medications, does that fit into this framework at all.

DR. SOX: I would think that it would, if we could identify a group of patients who either change medication or lower medication. We would probably have to analyze that group separately from those who withhold it entirely.

DR. DAVIS: Because there was some evidence that I gleaned in some of the papers about patients with white coat hypertension not necessarily getting no treatment, but getting less treatment than those who had office measured hypertension.

One other question I had deals with the second analytic framework. And it's a similar sort of question. And I'll wait for you to put up the overhead. In that box between number 2 and number 3 where you have physicians maintain treatment despite

high office BP, what about inserting the words "or reduce" after maintain? There was one study that again, talked about patients with white coat hypertension or patients who had been monitored with ambulatory blood pressure monitoring who had less intensive drug treatment compared to those with office based blood pressure, but not necessarily getting no treatment.

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DR. SOX: I would think that would be a particularly important insertion in the analytic framework, and we should, we should I think note that and then when I go back and change it, so that we can have the record reflect that.

DR. DAVIS: Thank you.

DR. SOX: Ken.

DR. BRIN: Hal, I have a couple comments on the framework. The first one is that many of us in clinical practice don't see presence or absence of ambulatory blood pressure monitoring as the only option. Many of us have patients that take their own

blood pressures outside the office and one of the questions that I would raise is one as to, is ambulatory blood pressure monitoring a more effective manner as opposed to what many of use as the routine, which is having the patients take there own blood pressure, whether it is their own home blood pressure machine or going to their pharmacy and using one of those machines, whether valid or not. And that's what the clinical treatment algorithm is for many of us and I would think that, I would hope that we will address that at some point, because I think that's relevant.

DR. SOX: Yeah. There is some data about

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the relationship between office blood pressure, home blood pressure, self monitoring and ambulatory blood pressure monitoring, which we should address.

DR. BRIN: The second comment has to do with what appears to be question number 2 on each of the algorithms, which is, do physicians withhold treatment when blood pressure is normal? That would

suggest that the question we're raising has to do more with physician behavior than with evidence based medicine and I'm a little concerned about that, because if in fact the evidence would suggest that physicians should or should not, then I think we should put in there an assumption that physicians will, as they generally do, treat according to what the general consensus in literature is.

I'm concerned that if in fact the sense is well, physicians aren't going to listen to it anyway, if the evidence is overwhelming that they should, then we should be setting guidelines or making recommendations based on ideal or proper practice of medicine, as opposed to whether behavior is influenced, behavior should be influenced, and I think the literature supports them, but when we come out with strong evidence based medicine to suggest a change in physician behavior, behavior changes. So I

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would be uncomfortable with a decision based on gee, are they going to change their behavior.

DR. SOX: Of course there is some

circularity there, because you can't have good guidelines, you know, evidence based guidelines without doing studies in which physicians withhold or don't withhold. As a practical matter, I don't think there is any evidence on key question 3, and so I believe that we should assume that physicians would treat according to office, according to home blood pressure, which is the best case assumption, for seeing an effect of ABPM, in other words, giving it the benefit of the doubt so to speak. I think that's the fairest way to proceed, because we won't have any evidence on that score, at least none that I'm aware of.

Great. Other questions before we go on? Christine?

MS. GRANT: This was just a question more on the ground rules. Each of these questions relate to ABPM and treatment, and so, are we not looking at or being asked about ABPM in relation to extending accuracy, specificity, sensitivity of diagnosis per se?

DR. SOX: Yeah, I guess the answer is no,

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that we're interested in measuring the impact of the intervention on health care outcomes.

MS. GRANT: But as a technical coverage consideration, specificity, sensitivity of diagnosis is not a coverage issue that we're being asked to look at?

DR. SOX: Well, the way that we have developed our interim guidelines, which are going to be reviewed by the Executive Committee tomorrow, and so they're not really, you haven't seen them yet, is that we try to infer the, if the effects of sensitivity and specificity on health care outcomes, which we did in our November 7th meeting where we reviewed PET scanning, so I guess the basic answer is, sensitivity and specificity by itself, we don't think is important unless we can see a train of logic leading to better health care outcome.

DR. TUNIS: I would just add to that that it's certainly legitimate to, you know, to raise that

point. You know, the framework for evaluating diagnostic tests is not a final framework that has been formally adopted by the MCAC at this point, so this whole isse of, you know, if you want to raise the issue that, you know, by itself the increased accuracy, sensitivity, et cetera, of this, of the

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technology is sufficient in your view in some way to justify the clinical use or coverage or something, that point is not out of bounds, so you can make it now and you can make it again, and it will be taken into consideration.

MS. GRANT: Well, I just, again, wearing the consumer rep hat, I would say that if we're not looking at that, let the record show we're not looking at it as a diagnostic tool per se, because then we are not really looking at the under treatment of hypertension out there, we are really looking at this very specific connection between ABPM and outcome, as you were describing it, so we're not looking at that universe. I don't know what to make of that, but I just need to know that we are not

looking at that today.

DR. SOX: Well, again, our framework are health care outcomes that are tangible, and I guess the implicit assumption is that it's not worth doing a test unless it alters your management in a way that you can predict will change the patient's health status for the better, which is a pretty important principle of medical practice. We occasionally do diagnostic tests because we think the results may make the patient feel better about themselves, even

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though knowing the results isn't going to help us change the patient's health status other than feeling better about themselves.

Any other questions before we go on? Well, in that case, I would like to ask Thomas Pickering, who is a -- to introduce himself. He's a professor of medicine at Columbia, I think; is that right, Tom?

DR. PICKERING: Nearly.

DR. SOX: Nearly.

DR. PICKERING: Where would you like me to stand, over here? I have overheads.

DR. SOX: Whatever is comfortable for you.

DR. PICKERING: Thank you very much. It's a great pleasure and privilege to be able to introduce this topic to the committee. Let me begin by just saying who I am and why I am here. My current appointment is actually director of the integrative and behavioral cardiology program at Mount Sinai Medical Center, where I have just been for about six months. And I am a specialist in hypertension and my practice is focused in hypertension, and I have had an interest in ambulatory blood pressure monitoring going back to the late '70s and have published numerous papers on

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it and also a book on it, and have used it for research and also more recently for routine clinical practice.

I have been involved with a number of physician statements on the subject, firstly the national high blood pressure education program

statement which I think was in 1990, then the American College of Cardiology in 1994. I chaired a committee for the American Society of Hypertension which recommended its more widespread use. More recently, I was one of the committee members for the joint national committee of the national high blood pressure education program, which is the sort of official guidelines for treating hypertension in this country, and wrote the sections on self monitoring and ambulatory monitoring. And I also petitioned AHRQ to examine both ambulatory and home monitoring for technology evaluation, and that process is currently going on.

I am on the advisory board of a patient oriented web site called LifeClinic.com, which deals with a variety of life style issues such as obesity, smoking, diet, diabetes and blood pressure, and this is a subsidiary of Spacelabs Medical.

So, what I would like to do is begin by

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introducing the general topic of hypertension and

this slide is probably familiar to you but shows the continuous relationship between the level of blood pressure and the risk of strokes and heart attacks. These data of course were obtained with the conventional clinic measure of blood pressure which in general has served us very well over the years, but when we measure clinic pressure what we are really doing is using it as a surrogate for what we consider the patient's true blood pressure to be, which is the average level of pressure to which circulation is exposed over many years.

Dr. Sox mentioned some other surrogate measures or intermediate markers that we're interested in, for interest, left ventricular hypertrophy, carotid artery atherosclerosis, and mitral albuminuria. All of these are also related to the level of blood pressure, whether it's measured in the clinic or by other techniques such as ambulatory monitoring, and many of them have also shown to been independent predictors of cardiovascular morbidity. May I have the next slide please.

Now when we talk about the conventional

measurements of blood pressure, even though there are guidelines issued by the American Heart Association

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and other bodies about how blood pressure should be taken, what tends to happen in practice is shown here, which is terminal digit preference, that is, physicians which includes not only family practitioners but also specialists, tend to read to the nearest zero. We're supposed to read to the nearest two, so there's an inherent error in many of the office readings that are taken in practice. Next slide please.

Not only that but the way in which the physician or whoever is taking the blood pressure interacts with the patient can also have a significant impact on the pressure that's recorded. This was from an experimental study in which two clinic measurements were taken in succession, and between the first and the second measurement, the patient was either given no instructions or they were told that pressure was likely to increase, decrease

or not to change, and this shows what actually happened between the first and second reading. So as you can see, there's a difference here of 12 millimeters mercury purely on the basis of what the